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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/254,152    02/26/99    HIGASHIYAMA

K    001560-344

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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:    12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<p align="center"><b>Office Action Summary</b></p>	Application No. 09/254,152	Applicant(s) HIGASHIYAMA ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2000.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 14, and 19-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 19-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Receipt of the Amendments and Remarks submitted September 22, 2000 is acknowledged.

#### *Claim Rejections 35 U.S.C. § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 19-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation in claim 19, "wherein the ratio of the nitrogen source derived from soybean with respect to the total nitrogen source in the medium is at least 86%.", lacks support from the specification as originally filed.

3. Claims 37-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The mead acid containing oil or composition has no support in the specification as originally filed.

#### *Claim Rejection 35 USC – 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shinmen et al. and Shimizu et al.

Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 21 % and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 0.37 with respect to desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35 % or less and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 1.2 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al.

Shinman et al do not teach expressly the percentage of nitrogen source derived from soybean products herein. However, considering soybean meal is one of the only three preferred

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nitrogen sources, the further optimization of nitrogen source, i.e., employ soybean meal for at least 84% of nitrogen source, is considered within the skill of artisan.

3. Claims 13-14, 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al in view of both of Shimizu et al and Barclay.

Shinmen et al. teach an unsaturated fatty acid-containing oil obtained from culturing of microorganism *Mortierella* contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. do not teach how much of 24,25-methylenecholest-5-en-3 $\beta$ -ol is present in the oil. Shinmen do not teach the employment of such oil in food products including baby food and animal food.

However, Shimizu et al. teach that unsaturated fatty acid-containing oil obtained from culturing microorganism *Mortierella* has 24,25-methylenecholest-5-en-3 $\beta$ -ol which has not been found in nature, i.e., not found in any natural food such as breast milk and its biological activity and toxicity have not been fully evaluated. See, particularly, the abstract on page 481. Barclay teach the employment of arachidonic acid containing oil obtained from culturing microorganism *Mortierella* for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to modify the unsaturated fatty acid-containing oil of Shinmen et al. by removing the biologically unknown compound, i.e., 24,25-

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methylenecholest-5-en-3 $\beta$ -ol and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement.

A person of ordinary skill in the art would have been motivated to remove 24,25-methylenecholest-5-en-3 $\beta$ -ol from the unsaturated fatty acid-containing oil and employ the modified oil in food products such as baby food and animal food or in nutritive dietary supplement because the biological activity of 24,25-methylenecholest-5-en-3 $\beta$ -ol is not known and it would not be safe to use such oil in baby food. Methods of removing the compound such as chromatography separation or modification of fermentation conditions are considered within the skill of artisan. Furthermore, employment of unsaturated fatty acid-containing oil in food products are known.

Applicants' remarks submitted September 22, 2000 have been fully considered, but are not persuasive for reasons discussed below.

Regarding the remarks about the process claims 19-29, note that the references teach a method of producing arachidonic acid containing oil by culturing with aeration in a fermentor a microorganism belonging to the genus *Mortierella*, subgenus *Mortierella*. See page 15, left column, particularly, the brief description of Fig 3. The employment of soybean meal for 84% of nitrogen source is seen to be obvious as discussed above.

Regarding the remarks about the composition claims 13-14 and 30-36, note that the references teaches that the arachidonic acid containing oil obtained therein may have 18-68 % of arachidonic acid depending on the cultivation time. See Fig 3b. Shimizu et al. teach that oil obtained from similar condition has a 24,25-methylenecholest-5-en-3 $\beta$ -ol composition ration about 25%. See the table on page 482. Further, 24,25-methylenecholest-5-en-3 $\beta$ -ol is known to

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be a new compounds not found in nature before, a person of ordinary skill in the art would certainly be motivated to reduce the amount of 24,25-methylenecholest-5-en-3 $\beta$ -ol in any food products, particularly in baby food products, since the property of 24,25-methylenecholest-5-en-3 $\beta$ -ol is unknown. A person of ordinary skill in the art would have reasonably expected not to employ a compound in food product without a fully evaluation the property of the compound.

Nothing unobvious is seen in the claimed invention.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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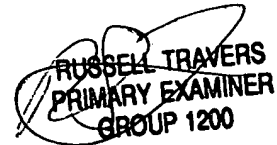
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

November 29, 2000

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200